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Collaborative co-design of emerging multi-technologies for surgery

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ABSTRACT

The EU Research Training Network on Augmented Reality in Surgery (ARIS*ER) was established with two aims: (1) to develop next-generation novel image guidance (augmented reality based on medical images) and cross-linked robotic systems (automatic control loops guided by information sensed from the patient) and (2) to educate young researchers in the user-centred, multidisciplinary design of emerging technologies for minimally invasive surgery (MIS) and intervention radiology. Collaborations between engineers, Human Factors specialists, industrial designers and medical end users were foreseen, but actual methodologies had to be developed. Three applications were used as development vehicles and as demonstrators. The resulting teamwork and process of indentifying requirements, finding solutions (in technology and workflow), and shifting between these to optimize and speed development towards quality of care were studied. The ARIS*ER approach solves current problems in collaborative teams, taking a systems approach, and manages the overview of requirements and solutions, which is too complex to manage centrally.

1. Introduction

In 2004 the Augmented Reality in Surgery Research Training Network (ARIS*ER RTN) was established, with the aim of investigating and developing next-generation novel imaging guidance (augmented reality based on medical images) and cross-linked robotic systems (automatic control loops guided by sensed data from the patient). In the ARIS*ER vision the surgeon can look directly into the patient's body. A liver surgeon would be able to see through the organ's surface during surgery, perceiving its vessels inside and a tumour in spatial relation to the current tool locations. Information about the current locations of tissues and tools or the properties of tissues would be presented to the surgeon or used to feed automatic control loops. Robots would assist him in conducting tasks with precision or with repetitive actions. Interactions would be easy to learn and understand; the selection of supportive information would require low levels of cognitive effort, so that the surgeon can fully concentrate on primary surgical tasks; the system reduces human errors and supports recovery from errors.

ARIS*ER focussed primarily on minimally invasive treatments (MIT), because these are most in need of better support. Increasingly, traditional surgical procedures are being replaced by MIT because patients experience fewer complications and hospital stays are reduced. A faster recovery time and substantially improved cost-effectiveness for the hospital and the public have been established (for example, see [1] concerning radiofrequency ablation). The development of MIT was facilitated by breakthroughs in imaging technologies and robotics [1]. However, these procedures also raise new problems. There is a lack of direct visual and palpation feedback, a need for complex eye–hand coordination, and for operating with tools without force feedback. Workflows are often more cumbersome, for example because of limited workspace and the distance between the surgeon's hands and the operative field. There is always a chance that reversion to an open procedure will be necessary if complications arise. ARIS*ER aimed to improve this situation.

In addition to its scientific aim, this EU Marie Curie RTN was also meant to educate young scientists at the PhD and postdoc level, and broaden their skills in multidisciplinary team work, which is particularly important to the development of emerging medical technologies. This is also of economic importance to the EU.

Next-generation novel imaging guidance and cross-linked robotic systems require the development of several emerging technologies, and these technologies have to be integrated to work together. User-centred design was key, because the prime aim was an optimal information and user-system interaction, seamlessly supporting medical workflow.

The collaborative design methodology which would allow these emerging technologies to act as a coherent whole and to be tailored to the user and workflow was not trivial. Several basic

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technological innovations were needed, and these had to be integrated into compiled systems. Additionally, gaps between the disciplines involved had to be overcome.

(1) *Technology innovations:* In 2004 ARIS*ER was still a vision – only immature and unreliable tools for real-time 3D-tissue (4D) navigation in soft tissue were available, and functionalities were lacking or immature.[1] ARIS*ER aimed to provide next-generation imaging support. Over the years image guidance has moved from 2D (e.g. graphical user interfaces, radiology pictures, ultrasound presentations), to 3D datasets (e.g. MRI/CT) and towards 4D (3D locations presented as a function of time). 4D is 'flowing 3D data' constantly showing the actual locations of tissues and tools. This was the goal for ARIS*ER. The idea was to bring it even further, providing a representation of the operative space (tissues, tools, lesions, tissue properties – in real time and place) and the possibility for the user to navigate in this space. In particular, real-time deformed, registered and segmented tissues should be shown, as well as tracked tools, and also real-time haptics, real-time robot guidance, etc. Technological breakthroughs are needed for this, but so are new approaches from Human Factors and user-centred design methodologies, since user requirements in relation to such interactions have scarcely been investigated.

(2) *Integration*: Klein et al. [10] formulate the problem this way: "The key challenge raised by the collaborative design of complex artefacts is that the design spaces are typically huge, and concurrent search by the many participants through the different design subspaces can be expensive and time-consuming because design issue interdependencies lead to conflicts (when the design solutions for different subspaces are not consistent with each other). Such conflicts severely impact design utility and lead to the need for expensive and time-consuming design rework." Therefore, there is a need for coordination of a wide range of roles in the process of design and development: a product manager to talk with physicians, a system analyst to develop specifications, a project manager to coordinate the team developing the system, and a team of engineers to develop the different aspects of the system. An inter-disciplinary research team has a vague or nonexistent definition of these roles, which are to be assumed by different individuals during the course of the project.

(3) *Gaps between the disciplines:* Examples of inter-disciplinary education are gradually increasing in the engineering-medical domain, and in industrial design for medical applications. However, in 2004 it was not yet possible to select team members primarily on this criterion; too few were available and other criteria were important, e.g. scientific excellence. Therefore, several of the team members had a background in a single discipline. A multidisciplinary training programme for engineers and Human Factors experts, industrial designers and medical users was required. Not only to train the researchers in team work, but also to develop the methodology through learning by doing. Its development became a parallel task for the project, and the final approach was called 'collaborative co-design'. This new approach is the focus of this paper.

The gradual development of this collaborative co-design approach, in addition to the other scientific work and as a result of active investigations, learning by doing, and intentional courses and workshops, will be reported. The approach is centred on defining system requirements and finding solutions, in a user-centred way, and maximizing innovations in compiled technologies in order to serve healthcare in the most effective way. The benefits of this approach, as compared to the real-world development of complex systems (Section 8.1), and the consequences for pre-graduate training (Section 8.2) are identified.

2. Educational structure of ARIS*ER

The basic educational format in Marie Curie RTN is PhD-level and postdoc studies involving research combined with courses. Dedicated courses were developed specifically for this group. These included a 3-day robotics course with lectures on a range of topics, such as visual servoing in surgery and collision detection. A laparoscopic training programme for all participants was arranged at a partner hospital, with basic training setups and slaughterhouse samples; One of the industrial partners provided training in medical software development and the roles of different groups, such as product management, engineering, research, regulation, and issues of intellectual property. Additionally, in the first user-centred design course one of the assignments was to design a system in groups on a topic addressing navigation issues, based on explained and teacher-guided 'group-ware task analysis techniques' [11]. Another course example is given in Section 5.5.

Oral and written presentations were practiced in the summer sessions, where books were produced [12–15] External researchers gave guest lectures and contributed chapters.

The required emerging technologies were to be developed primarily by 16 hired PhD and postdoc researchers. The ARIS*ER PhD students were also enrolled in local PhD-programmes and received the customary mentoring or coaching. They had exchanges with local experts and took part in domain-specific international conferences. Several researchers (those who worked for an industrial partner or the participating hospital) were guided by PhD supervisors from renowned universities in the area. By adhering to this 'normal' model the researchers received a proper education and work experience as academic researchers. The core research findings in most of the scientific output remained in the domains of academic expertise, although the motivations for the study or the core functionality to be developed originated from the multidisciplinary work. For example, automatic segmentation was developed to show the surgeon vessel structure [16,17].

A difference in the education of ARIS*ER early stage researchers arose from their tight integration into the ARIS*ER consortium. They were all actively involved in the process of finding functionalities and required properties, solving technical problems, and optimizing the design decisions in building a complete system. They would contribute to working prototypes, which were actually tested, and they got feedback from end users. This practical relevance gave their personal research project a deeper meaning.

Working with a team of PhD students and postdocs requires specific management, which is quite different from working in industry where employees can be directed to carry out certain research or design tasks. PhD students require more freedom and the opportunity to explore independently within a selected area. The PhD student also has to focus and follow a suitable timeline in order to generate sufficient quality output (e.g. articles, patents). Postdocs are less dictated by this, but they also need to publish and focus. This makes it a bit complicated to organize all the development work and divide it among the researchers. Gaps arise, some quite late, because pressuring the PhD students is not an option. The staff put all their effort into keeping the project on track as a development project, with deliverables, tested demos, and

[1] When the project began several 4D navigation systems existed and many have been improved since then; others entered the market during the project. Some examples are ExacTrac® by Brainlab [2] described by Hatano et al. [3] and later evaluated by Wurm et al. [4] and Li et al. [5]. Ascension [6] produces 3D catheter tracking sensors, compatible with fluoroscopy, for cardiac procedures, which combines to result in 4D image guidance. 3D Ultrasound (4D if used in real time) was introduced a few years ago, e.g. by Philips [7]. Another example is a 'labour progress monitoring system' providing decision support for obstetrics [6]. Examples early in the project period came from Esaote: Virtual Navigator [8], and later Traxtal: PercuNav™ [9]. However, none of these systems provide the properties envisioned by this project, even the latter two do not offer 'real-time deformable registration'.

prescribed levels of realism. Some staff members were assigned to fill in gaps with additional investigations (e.g. many of the technical integration documents were made and managed by a staff member, see for example [18]). The target was to deliver an outcome which was highly rated by end users, was tested, and was preferably marketable.

3. User-centred design in ARIS*ER

ARIS*ER was started with the aim of applying user-centred design. There are many 'official' methods (e.g. ISO 13407) [19], as well as 'experimental' methods (still immature but very promising) and established good practice. All these categories were considered for ARIS*ER, and it was clear from the start that new methods would have to be developed as well.

ISO 13407 describes the user-centred development process and the definition of requirements as well as the need for multidisciplinary design and user involvement, understanding the context, and conducting user studies. Another important overview is by Steen [20], who describes historical developments from the 1960s and 1970s which began in Scandinavia and were called participatory design; in principal a collaboration between industrial workers and ICT experts. Steen extensively discussed a range of older and newer methods, for example, empathic design [21] and contextual design [22]. Over the past 40 years the participatory and other co-design methods have developed considerably (see [23]). At present greater industrial and academic interest is speeding up developments. Increasingly, new areas of collaboration are being introduced to the principle, with generally positive impact on user satisfaction about new products, systems or organizations in work. In this paper, all user-involved design methods will be called co-design.

In engineering practice the application of this type of method, though becoming more common, is still often limited, which has resulted in a frequent mismatch of technology to human needs. This causes a situation Bogner [24] has been warning about for the last 15 years, that human error is related to increased system complexity. Quite often engineers will begin developing something new based on ideas they have derived from the field or simply from their own insights. Although there are usually regular consultations with doctors and investigations into relevant issues, the investigations tend to be informal. Formal studies are also performed (e.g. measurements of actual tissue movements, eye–hand coordination, etc.) in relation to the new technology. Very often, however, only the tailoring of the chosen solution is approached in such a formal way, while the earliest stage of problem definition is not. Besides methods for co-design (e.g., for workflow analysis and workflow redesign) user interface design methods are also important (e.g., for intuitive interactions), as are methods from system ergonomics (e.g., to design for safety), and cognitive ergonomics (e.g., to design according to human behaviour strategies).

The aspects from cognitive ergonomics are particularly crucial. Simply talking to users and asking for their views on systems requirements is not an option. As Flach et al. [25] emphasize, "In complex work domains, one must be sceptical about whether even the experts have a complete model of the task constraints". This becomes clear when "studying cognition in the wild, the researcher must simultaneously construct a model of the ecology (task environment) and the belief system (psychology). In many cases, people studying cognition in the wild discover that behaviours that at first appeared to them to be "irrational" are later discovered to be perfectly reasonable as they get a deeper understanding of the work domain constraints". Flach and colleagues stress that to understand how and what should be presented an in-depth understanding of work activities, as well as human information processing and decision criteria is required.

3.1. Conclusion on user-centred design

In ARIS*ER the aims were (1) to involve end users from the earliest stages of defining system properties, by selected methods (e.g., from the overview by Steen [20]) and newly developed co-design methods; (2) to apply information design theories (what to present); (3) to apply interaction design (how to present and how to control); (4) to conduct system and strategic design (overall design process); (5) to conduct Human Factors; (6) to use safety management methods (tailored to 'safety by design'). New knowledge and methods were developed in all six sub-disciplines.

4. ARIS*ER research and development activities

4.1. Overview

There were six main stages in the project:

1. Vision (user- and technology-driven). As a way to direct the initial development as well as longer-term goals, the ARIS*ER vision (summarized in Section 1) was used.
2. Design a universal system and define the components/ disciplines needed (Section 4.2).
3. Define general key design issues, from a user's point of view, for such a system (Section 4.3).
4. Identify three medical applications which could benefit significantly from such a system. These applications should clearly demonstrate the scope and potential of the ARIS*ER technology (Section 4.4).
5. Split up development in these three applications: For every application conduct user and workflow analysis, develop all parts for one or more applications; develop user-centred multidisciplinary design approach for system and user interface; crosslink user needs to steer developments; define integrated systems (and user interface) and, matching new workflows, build integrated demos and prototypes and test these (Sections 4.5.1–4.5.3).
6. Investigate whether the developed parts and user-centred design approach could deliver another system for an 'ARIS*ER-suitable' medical application in a reasonable timeframe (Section 4.6).

4.2. Design a universal system and define the components/ disciplines needed

"A number of key technological problems were defined early in the project which would need to be addressed in order to provide essential technological building blocks. This part of the project was executed in a bottom-up fashion, while the higher level demonstrator and application development was performed in a top-down fashion based on the requirements during the user-centred co-design work" wrote Samset et al. [26]. At the beginning of the project a system model was made (see Fig. 1).

The components had to be integrated into a single technology platform. Construction of this started immediately. The platform built on previous work from one of the research groups, a 'liver surgery planner' [27–29].

4.3. Define general key design issues, from a user's point of view, for such a system

Two focus group interviews with medical specialists were held, introducing them to the possibilities of the envisioned ARIS*ER technologies. Through drawing assignments and moderated peer-to-peer discussions they depicted the key design issues for such

a system. Next, they identified several applications from the spectrum of represented domains (e.g. liver surgery, brain surgery, urology, radiology, etc.) and indicated how these could benefit from the envisioned technologies.

4.4. Identify three medical applications for development

The data were integrated and several interviews were held with a number of other doctors to explore the proposals in greater depth. The board held several discussions and more formal interactive workshops to match up with technical possibilities. A proposal with five options was written and the advising doctors chose from this list. The chosen applications were: percutaneous radiofrequency ablation of liver tumours, laparoscopic liver resection, and endoscopic mitral valve replacement or repair (see Sections 4.5.1–4.5.3 and 5.2–5.4). It was decided to limit the number of concrete applications because user-centred research has to be concrete in order to come up with suitable solutions. Also, technology development requires concrete specifications linked to actual work. In this project the intention was not to develop technology for three applications only, but to develop components that would be generally usable, and would easily generate next versions for other applications for which new, tailored user interfaces would be needed. (Conclusions on generalizability are given in Section 4.6.)

4.5. Developments for the three applications

4.5.1. Radiofrequency ablation of liver tumours

In radiofrequency ablation (RFA) the intervention radiologist or surgeon positions a needle into the target liver tumour. The tumour is then ablated by local electromagnetic energy disposition. This was the first application to be tackled. For RFA all of the essential building blocks depicted in Fig. 1 were relevant and were therefore addressed in development.

The development of technology building blocks proceeded from the ARIS*ER vision. One of the UI researchers[2] studied RFA interventional work and context. Jalote-Parmar fed field data into a huge poster to communicate her findings to the other researchers. There were six columns showing work phases (before, during and after treatment) and 13 rows with the main factors, including process/system descriptions, physical constraints, and cognitive factors; underneath these were ideas for changes in process and equipment. Every cell was filled with one to nine aspects. The newly developed analysis and communication method was named the 'Workflow Integration Matrix' [30–33].

As a direct result of this meeting, background technologists could define the required technologies to develop. Image processing and fusing particularly needed to know which imaging modality they were developing for, and this could be decided based on user needs.

At the end of the second year an initial technology-driven demo was delivered, based on the ARIS*ER vision and some preliminary UI researcher guidance [34] (see Fig. 2a). The demo was used in evaluation studies [35]. The analysis of context-of-use was refined, with a focus on the intra-operative navigation process [36]; the user requirements were defined for evaluation purposes [37].

Next, different solutions for the user interface were developed, tested and compared [35]. One solution from Stüdeli et al. [35] is shown in Fig. 2b. It shows a 3D segmented liver and three orthogonal slices. Another solution by Jalote-Parmar et al. was to provide three screens: at left, the ultrasound with augmented critical structural information and the needle in view; at right, the original CT dataset; and in the middle screen a fused, slightly see-through image combining 3D CT and ultrasound [32,33].

Robot needle placement was designed, built and tested on a phantom [38]. The same 3D data and registration technologies were used to direct the robot. All four demonstrators for RFA support ran on the same platform and technology building blocks.

The developed technologies were matched to user needs, but in the last iteration there was a conflict between the two concerning the possibility of actual testing in a clinical setting. This is described in Section 5.2.

4.5.2. Minimally invasive liver resection

In liver resection the surgeon cuts part of the liver away, removing a tumour and an extra margin of tissue. This was the second topic to be tackled by the UI researchers. Once again Jalote-Parmar made a Workflow Integration Matrix [30–33] which was communicated to half of all ARIS*ER members in a 4-h workshop session in 2006. Meanwhile Lamata, a new member to ARIS*ER, had begun field observations and had identified many issues with an informal ethnography approach. The two researchers fused their combined insights and developed the 'Resection Map', a 3D guide for resection [39,40] (see Fig. 4). During the rest of the process intense co-design work and multiple demo evaluations were conducted with the lead surgeon. Some background technologies were needed, e.g., segmentation, so several other researchers joined the team [16,17]. To actually treat patients guided by the prototype, the pre-operative data for one patient were sent to the 'segmentation partner' and then sent back for use by the surgeon for treatment planning and use in the OR (this was first done in tests and is now done in some regular treatments). The team faced severe technology challenges and had to carefully balance solutions and requirements, as described in Section 5.3.

4.5.3. Endoscopic cardiac surgery

A workshop with half of the consortium was held in 2006. It was prepared by ethnography (observations and interviews) in several hospitals by an engineer and a UI researcher. The workshop was conducted around a large matrix. The columns were inspired by the Workflow Integration Matrix [30–33], and showed the main steps in the procedure. The rows were blank, to be filled in during the meeting by engineers, a Human Factors specialist, an industrial designer and several surgeons. The topics of analysis were different, and therefore the rows were. As Stüdeli explains: "In endoscopic cardiac interventions the team consists of several subteams (surgical team, anaesthesia team, scrub nurse team and the perfusion team) with two to four team members each. I therefore reviewed and adapted the design tool from a single user setting to structured collaborative use, with specific analysis of all the roles and the safety critical aspects in the roles and tasks" [41]. A number of urgent problems in surgery were identified, as well as solutions. Definitive choices about what exactly to develop were made later. One solution was about the control and positioning of the balloon catheter (endoclamp); the basic concept was established during this workshop. Development took place over many collaborative meetings, with the four researchers developing their own parts and conducting background research. Several studies of fundamental technology building blocks were conducted with other researchers (e.g. [42]). The prototype was evaluated in user tests in phantom and animal studies [43,44].

[2] UI researchers were industrial designers/Human Factor specialists, in charge of (1) involving end users from the earliest stages of defining system properties by selected methods and developing co-design methods; (2) applying information design theories (what to present); (3) applying interaction design (how to present and how to control); (4) conducting Human Factors, also called ergonomics; (5) developing and applying safety management methods (tailored to 'safety by design'). They also had an important role in (6) conducting systems and strategic design (overall design process).

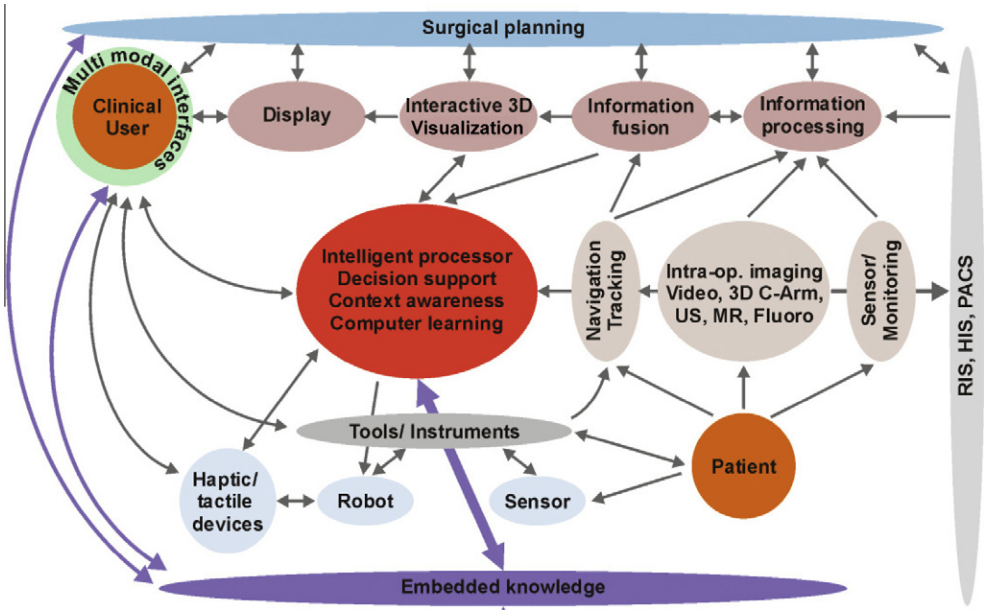

Fig. 1. Overview of the structural design of ARIS*ER system as collaboratively defined before strict design work began. The model remained valid for the duration of the entire project.

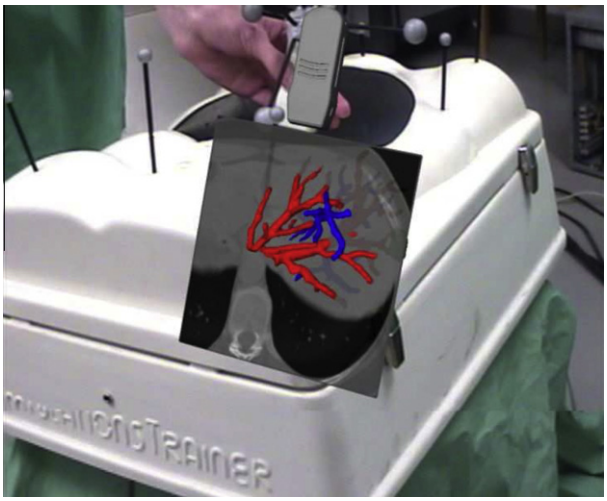

Fig. 2a. Screen shot from abdominal phantom demonstrator for radiofrequency ablation (RFA) [34]. Various modalities and virtual elements can be combined. The scene is viewed by the user through a head mounted display in 3D. The hepatic vessel tree is segmented from a pre-operative CT. The cut through plane in CT is inside this 3D structure, defined by the hand holding the RFA device (tracked US probe and needle).

4.6. Check for generalization of system and approach to other treatments

The advanced user interface workshop was held over 2 days. Another ARIS*ER concept was developed in the workshop, to check whether the developed essential building blocks and user-centred design approach could deliver another system for an 'ARIS*ER-suitable' medical application. Discussions also considered whether this transformation to another medical application would be 'easy' to conduct.

The course was organized around a clinical application that was new to all participants: Intra-operative radiation therapy (IORT) for advanced rectal cancer [45]. This treatment follows tumour removal, permitting local delivery of high radiation doses, while the treatment area remains accessible during surgery, thus avoiding exposure to neighbouring healthy tissue.

The additional educational aim of the workshop was to give the participants hands-on experience in different aspects of industrial design techniques for high-tech surgery: focused observation and interviews; problem definition; finding user interface and user-system interaction solutions and evaluating these; working with end users and in a design team; translating technical functions to human (cognitive) functions; understanding how humans behave when performing tasks and understanding how technology triggers behaviour.

On the first day in the hospital two surgeons and a radiotherapist explained the treatment, shown in a movie recorded previously, in an interactive group discussion. The participants were then divided into two groups. With guidance by UI researchers the surgery was analyzed and the design targets were defined. In a second meeting with the surgeon the group's findings were checked. This part was participatory research: the end-user helped the engineers to analyse.

On the second day two concept designs were developed by the two groups, setting out components, desired system behaviour, user interface and workflow. After less than 2 h the groups began storyboarding [46], a visual representation of the workflow and system in time. Experts in storyboarding guided the process, which is more than drawing. A lot of design work was done during this step, as making the storyboard requires decisions on design. Technologies were matched to user needs and optimized for feasibility. Details of the requirements were defined, including technical opportunities and limitations. This part of the process is collaborative design, including engineers, designers and Human Factors experts.

The storyboards were copied and sent to the surgeon. In a teleconference the workflow and system depicted in the storyboards was explained; the surgeon gave his reaction. The focus was on evaluating the system/user interface qualities and identification of what should be changed and how. This part of the process is co-design with end-user evaluations and optimizations.

The final concept was positively assessed by the surgeon, and was judged feasible for engineering. It was therefore concluded that the ARIS*ER components could be used in another medical

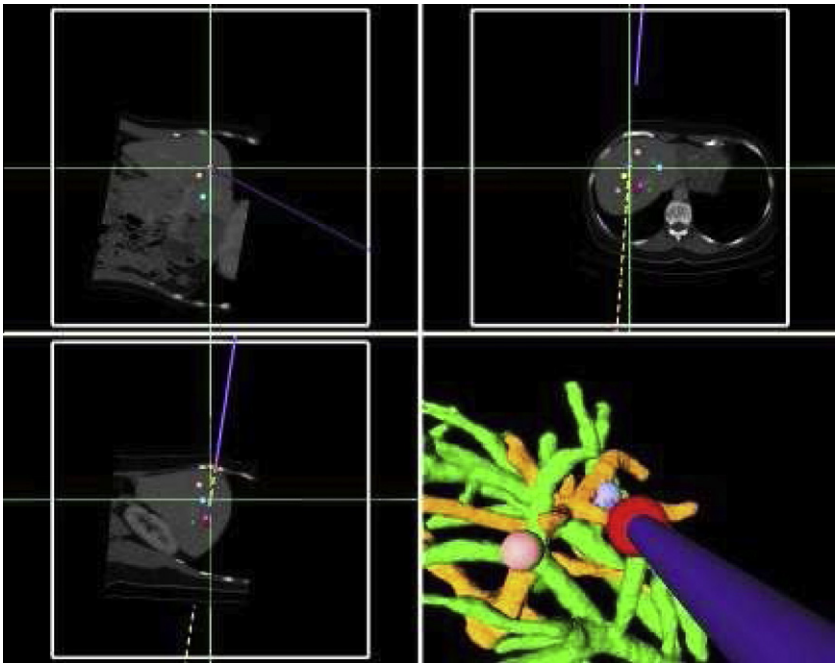

Fig. 2b. Novel visualization concepts from the second design loop. The treatment needle is presented in relation to the tissue locations, to support navigation (planning, orientation and movement control). The interface was introduced in Stüdeli et al. [35].

application, and that a new system/UI combination could be designed. Whether this would be 'easy' was uncertain. The team over the years had learned to collaborate and to trust each other and the course instructors. They knew about the need to communicate with users and understand their needs. They joined the course to learn how to conduct this. They trusted the guidance team's instructions, even when the methods were quite different from what they know as engineers. While the course was limited to instructions about what to do, the 'why' was provided by the results of the workshop. The participants were surprised and enthusiastic about the effectiveness the methods and had never experienced a doctor reacting so positively to an initial concept design sketch, neither had they expected to be able to deliver a complete concept, including medical workflow, in just 2 days.

5. Matching user requirements and technical possibilities

5.1. Deciding on task allocation between system and user

In ARIS*ER multi-disciplinary engineering was combined with industrial design and medical expertise. At its start, the model depicted in Fig. 3 was used to steer the design methods. In Freudenthal [47] it was explained that "This model is developed from two well known models for design, the basic design cycle (Roozenburg and Eekels) – a model depicting that in every design cycle there is a phase of defining criteria, synthesis and simulation, and a feedback loop with decision moment – and a second model on the iterative structure of the design process" [48].

These two models have been adapted for the specific situation where, parallel to interface design activities, core technology for the design will be developed, and presented so that the decision steps are synchronized. User requirements and the potential of technology are central to this model. In an iterative process physicians' desires for improved treatments and the technological solutions are matched. In these iterations the solutions become more defined, starting with the general notion that there are certain problems with current treatments, and that there is a potential technology which could solve the problems.

To give the reader an impression of how user requirements and technical possibilities were reconciled in terms of designed technical solutions, new workflow, and new cognitive tasks, we will examine one topic in detail: the registration of different image modalities or topological information. This was central to all applications. Registration was chosen because it was one of the examples where iterating back and forth many times was necessary, because technology was pushed to the limits and requirements and solution spaces had to be changed several times.

Registration is the fusing of information which is topologically 'equal' (approximately equal or 'exactly' equal, depending on the accuracy required). Registration can be done mentally, as is common when driving a car and using a paper road map: the human navigator finds his current location in the real world on the map, which is 'mental registration'. The task of achieving the state of registration is called 'orientation' (see [49]). Technological registration is when a technical system takes over this task and presents the information to the user in a way that fully supports orientation. For example, electronic car navigation systems show the car on the road, including location coordinates; the car is registered to the outside world and the driver's orientation is supported. The system also provides additional navigation support.[3]

5.2. Support of radiofrequency ablation of liver tumours (RFA)

The ARIS*ER vision informed the first iteration of RFA application. The idea was that surgeons (or interventional radiologists) need real time, deformable registration, so that both the tools and all the structures in the liver are in view in correct position, related to each other. Real time is needed because the liver moves with respiration. These movements influence work and actual human–system interactions, and applied navigation tactics related to motor skills. The liver goes up and down considerably and with significant speed even during the treatment, including during the

[3] A car navigation system also provides information about future actions, e.g. 'turn right in 200 m'. This information is not registration, but additional navigational guidance: it directs a person's control over movements in space. A complete set of navigation tasks can be found in [49].

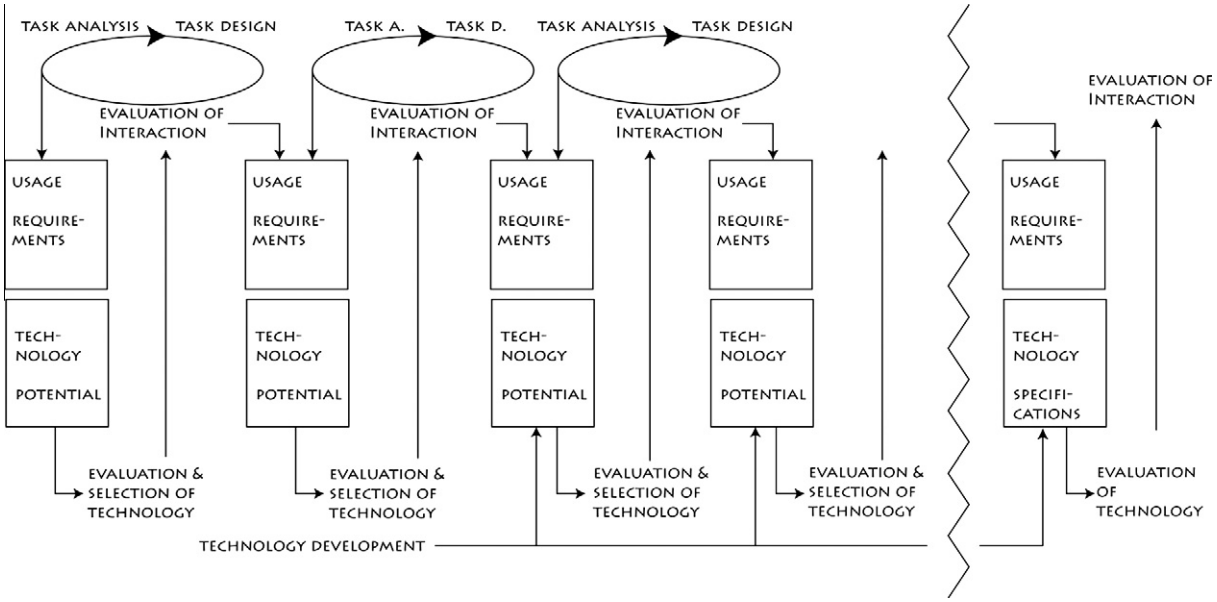

Fig. 3. Model of user-centred development in ARIS*ER in iterative steps as presented at the first summer school. The model highlights the matching of technological opportunities with user needs, tasks and user-system interactions and shows that potential technology should be selected in rounds, developed after selection and iteratively tested and improved. (Figure from Freudenthal A. Interface design and co-design in the medical domain. In: Abstract book, Augmented Reality. 1st European Summer School.)

puncturing. Deformable registration was being developed from the start [50]. Subsequent steps were taken to boost speed in calculation.

Freudenthal et al. [51] describe how, about halfway through development it became clear that calculation speeds would not be fast enough to follow the respiratory movements of the liver. There were two options for proceeding: to *not test realistically*, which would mean that the project would remain an academic exercise and in long-term development, or to *test in context,* validating both requirements and solutions (which cannot be done by studying the literature alone). This would require some major shifts in the approach to development.

The second option was explored, with additional research focusing on respiration and intervention from various angles. Workflow, the motion of the liver during respiration, priorities in providing information relating to impact on patient outcomes, and safety issues in introducing experimental software to the OR were also addressed.

The investigation and resulting design iteration were presented at the Healthcare Systems, Ergonomics and Patient Safety International Conference held in Strasbourg in 2008 [51]. The proposed approach [51] can facilitate clinical research with actual patients under strict safety controls as established by the advising medical experts, who collaborated through the entire process. Introductory phases respect current technology limitations while the impact on patient outcomes was the most decisive factor in choosing measures.

The principle solution component is to support the 'breath holding approach' only in the first test phase. Two approaches are currently used in RFA, with and without breath holding. In breath holding the anaesthesiologist administers extra oxygen, then clamps the tubes of the respiratory device for a few minutes. The liver is kept at a predefined height (depending on the chosen spot in the respiratory cycle). The breathing approach uses respiratory gating – the doctor makes a puncture when the liver passes a certain level. Breath-holding procedures are easier to conduct. There is one breath hold to register, then the patient breathes again, then treatment is performed during a second breath hold, in which the liver is in the same position (in the same phase in the respiratory cycle). Return to the same expiration position is very accurate, according to Olbrich et al. [52].

User interface guidance and options are given dependent on workflow phase (see Table 1). All parts will be integrated into one test system (except those in brackets: the robot and the models of treatment in phase III – 3 and 4). The purpose of action research is to test the experimental interfaces, which means *measurements* and these are indicated by italics, as are the *checks for patient safety*.[4]

The largest impact on patient outcomes is expected to come from helping the doctor to *identify the location to be treated*. Currently, most redo procedures (of the puncture or of the entire treatment) are related to the incorrect identification of the lesion area. The problem is caused by the inaccurate mental registration of real time ultrasound to preoperative image. "As a second measure [the doctors] would appreciate the marked tumour and the navigation aids. In designing the views with planning lines doctors find facts, actual distances in the images more important than a spatial 3D image... Most important are indication of distances of needle to tumour and compared to planning line, and end point indication" Freudenthal et al., [51]. These two functions will both be provided by deformable (but not extremely fast) registration.

Ultimately, doctors would still like to have the full ARIS*ER vision, requiring real-time deformable registration. But they prefer it to be developed gradually, in multiple iterations of design and testing, so that they can steer user interface and system choices and influence development. They would like real-time moving (and deforming) fusions because this will allow them to perform intra-operative checks much more quickly, without having to wait between cognitive steps, therefore allowing a more natural flow of actions, a close treatment-checking loop, and significantly speeding up treatments. This is beneficial for the hospital and society,

[4] Freudenthal et al. [51] explain "On the one hand FDA advocates involving users according to the latest Human Factors methods and insights (FDA, 2000) [53], which means, amongst other [things], early concept testing – in the context of real usage. ...[O]n the other hand FDA finds conducting treatment with not fully approved software unacceptable, for safety reasons (FDA, 2002) [54]." This dilemma was investigated, and a solution was proposed in [51].

Table 1
A summary of the redesigned workflow [51]. Parts will be integrated into one test system, except those in parentheses, which can be added later on. The workflow was finalized right after the parts were finalized in the 2008 workshop (see Fig. 8). Left column: Goals/tasks.[a] Right column: Solutions. Arrows indicate possible back loops in workflow. Italics indicate checks to safeguard patient safety measurements for the test phase. The current version of the image guidance tools can be found in Fig. 2b [55,56].

I. Pre-treatment phase	
1. Making a preoperative image	Posture same as in treatment, breath hold
2. Diagnostics – decide on treatment	As now
3a. Planning approach in treatment; the doctor simulates navigation and ablation and marks *define treatment posture*	Integrated system [18] for imaging – CT/MRI + segmentation of critical structures [16,17] + navigation aids [34]; possibility to mark plan and tumour in 3D
3b. Planning: building mental model	Richer interactions possible
II. Intra treatment preparations	
1. Preparing patient, including sedation, and hardware	Tracking of patient and tools and Registration of preoperative images to real time ultrasound [50] (and registration of robot to images [38,55])
2. Identifying the tumour	Is currently very difficult, high error rate; Will be easier task, because task 3a
4. Finding/fine tuning safe trajectory	Plan can be checked, changed or refined, same navigation aids in CT/MRI/US
III. Treatment: placing needle, ablation and quality check	
1. Targeting and puncturing through abdomen, and onto border of liver	Image technology including tracking of patient and tools and segmentation [18,16,17]; fusing of segmented CT/MRI with time real time ultrasound [50]; navigation aids [34]; puncturing in breath hold state; current location of tools related to plan; (option: needle placement by robot [38,55]) *checks for safety by Ultrasound, measurements by CT*
2. Same from liver border to tumour	The same system and interface, nearness indication, end point indication; again (or still) breath hold (option: by robot [38,55]) *Checks by US/CT*
3. Ablate	(Ablation progress presented from model [56])
4. Checking: sufficiently ablated?	(View to check compared to plan [56]) *measurements and checking by CT*

[a] The original workflow was very detailed, with some subtasks in III.1 and III.2: (1) aims toward the right direction; (2) punctures; (3) controls whether the needle goes the right way and (4) stops when the needle arrives at the target (or if it is off course the surgeon has to stop before entering carcinogenic tissue, to avoid spreading cancer cells).

but it also benefits the patient, since the burden of treatment is largely related to treatment times [51].

Conclusion (on registration in RFA): In this example technological advances did not develop as rapidly as planned. The example shows how a new definition of user requirements could be identified by closely re-examining workflow and other relevant topics. Apparently the high level of registration originally set as a goal was not crucial to major healthcare advances. Scaling down the goals for technology is expected to have an impact sooner, while also long-term development is better served by the early introduction of simplified versions of the vision.

5.3. Support of liver resection

Liver resection surgery is planned, but deviations from the plan are prepared because circumstances change during surgery. Lamata et al. [39] describe the principle challenges facing surgeons in this procedure: "Localization of the inner structures is very hard to anticipate by the surgeon, who therefore resects the liver very carefully, step by step, looking for the next inner structure to appear. Moreover, identification of these hidden structures is difficult since the operating field becomes really confusing due to the presence of bleeding and burnt tissue ... [this is] even more challenging when the laparoscopic approach is taken. The surgeon has to adapt to the limited workspace, and to understand the anatomy seen from the laparoscope, with organs at different scales and orientations and distorted views. He/she needs to mentally match some specific anatomical information from preoperative imaging studies to the laparoscopic operating field. And the surgeon cannot palpate the tumour location, as done in open surgery."

Lamata et al. [39] introduce their Resection Map, "a pragmatic solution to enhance liver resection accuracy and safety with an intuitive visualization of its critical inner structures." It was decided to develop such a map (also) for open liver surgery, where the problems are similar to those in the MIS approach: the lack of anatomical references while resecting the liver, the risk of harming a vein and causing an uncontrolled bleeding, and the risk of going beyond tumour safety margins. In MIS, the interaction of the surgeon is more limited, making his manoeuvres more complicated. The majority of liver resections are still open surgeries. The Resection Map is intended to help surgeons move from the open to MIS procedures.

The Resection Map shows the liver in 3D, including planned surgical route, key orientation landmarks and risk areas (e.g. vessels, tumours) (see Fig. 4). The surgeon must mentally register his current location on the map by locating the orientating landmarks and plan his subsequent steps by assessing distances and directions to the critical and target structures, and depending on the surgical plan. He will also constantly re-evaluate and mentally update the plan.

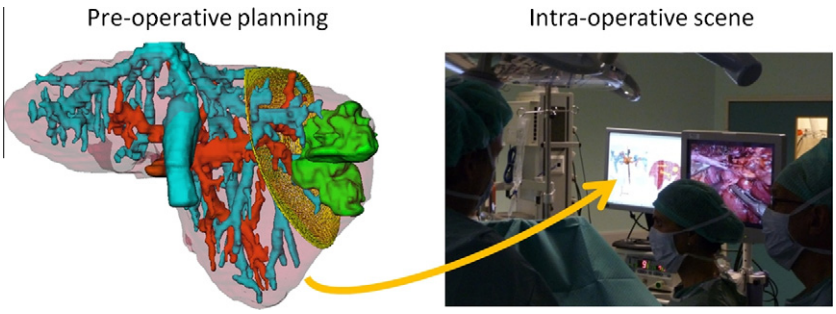

Fig. 4. 3D cartographic map of liver resection. At left, the plan (prepared by the surgeon); at right, the intra-operative scene. In the OR the surgeon has both a 3D and a cut-through view. The two can be adjusted by various parameters, e.g. angles. Current tool locations and current surgical view must be mentally registered to the map. [40].

In the first design evaluation, as expected, the surgeons missed the tool representation on the map. This had been an intentional choice for this first step. Lamata et al. explain, "Our proposal is to disregard it in a first step due to the extreme technical difficulty to acquire and register it due to the big deformations of the operation field ... The solution ... is the result of several design iterations between engineers, experts in Human Factors and surgeons ... To our knowledge after reviewing the literature, this is one of the first efforts towards the effective intra-operative guidance of hepatectomies. Related works are focused on the preoperative stage ... they are not designed for intra-operative requirements ... We believe that the Resection Map provides the necessary orientation information and confidence to the surgeon in order to perform a safer resection, progressing towards a solution to fill the existing gap between pre- and intra-operative visualization ... and allow[ing] a seamless integration in the OR" [39]. Because of its rapid introduction weak points in the design were uncovered early and will be tackled in the next steps [39]. The new user requirements identified in this round included the need to support intra-operative update of surgical planning due to new modules found in the ultrasound.

Conclusion (on resection): Lamata et al. explained the conscious matching of technology potential to user needs, thus prioritizing the need to make a clear impact on surgery rapidly, rather than developing the ultimate technology. As a result, the system is now in experimental use in several hospitals, and could be extended later with tool representations, once those are easier to provide. Meanwhile the system is being optimized to deal with new issues encountered in the user tests, conducted in real-life surgical situations.

5.4. Support of cardiac surgery – placement of endoclamp

In the 2006 workshop the most critical elements in minimally invasive cardiac surgery, mitral valve repair and replacement were identified [37]. One of these is aortic endoclamp placement and position control. The endoclamp is a balloon placed in the aorta that stops blood going to the heart, so that it can be emptied for surgery. During surgery the patient is placed on cardiopulmonary bypass. Transesophageal echocardiogram (an ultrasound technique with the probe in the oesophagus), can make it possible to monitor placement of balloon, but this is difficult to judge. Once the heart is emptied there is air in the spaces where blood normally is, making ultrasound monitoring impossible. However, the location of the balloon must be constantly monitored and corrected if necessary, as shifting is dangerous, especially because it could cut off blood flow to the brain. Currently monitoring is done indirectly, primarily by recording blood pressure differences in the right and left arms. Repositioning of the balloon catheter during surgery therefore requires major measures, which could slow the operation significantly.

To address this, "the designed system provides constant, real-time monitoring of balloon position during the entire procedure, automatic position control to a specified target (useful for initial placement and to correct migrations) and automatic balloon pressure control" [43]. The surgeon can see the correct position of the catheter tip, all along the aorta and down the descending aorta. He can see where the balloon is and is aided in placement. Any shifts are automatically corrected by a robotic control loop without damaging the aortic wall, and avoiding operative complications. The real-time registered 'catheter tip/balloon to 3D model' was presented on a flat screen (see Fig. 5). The surgeon is accustomed to the eye–hand coordination needed to steer or place the catheter with this type of view. Furtado et al. presented the problem analysis and design [43,44].

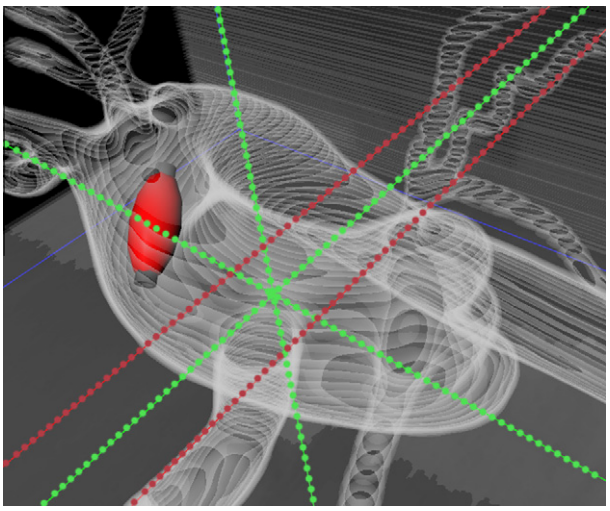

Fig. 5. One possible view on the user interface. It shows the aortic channel and within it the balloon at its current position. The balloon moves according to its actual position in treatment. The lines can be set to show the target and the allowed deviation from target position. Colour coding (red and green against the black and white preoperative image) shows when the balloon gets out of acceptable range or has not yet been correctly positioned. System and user interface were introduced in Furtado et al. [43,44]. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

Furtado and Lamata [42] explored and evaluated several of the available possibilities for registration. In the final tested prototype, registration of the 3D dataset to the body was required. This was done by several multimodal external markers, the connections between the animal's body and the images, which can be seen on the MRI and in CT imaging. One sensor coil was mounted on the balloon and was tracked magnetically. New software was also needed. Data could be acquired at 40 Hz which is sufficient to follow the treatment movements.

Conclusion (on registration in cardiac surgery): In this example the user requirements for registration did not have to be changed, and technology could be matched to user needs.

5.5. Support of intra-operative radiation therapy for advanced rectal cancer

The workflow of IORT for ARC was analyzed in the workshop and integral support for all stages was sought [45]. Several quite different support systems were explored and evaluated. One central task in conducting this therapy is the mental registration of the available preoperative image to locations in the body in order to compile a list of other tasks, e.g. assessing current treatment progress; installing the treatment tube in the correct location; being able to conduct research and education about best practice. All these tasks require exact knowledge of actual treatment locations. Especially the latter two tend to remain uncertain.

The pelvis is empty because the tumour has been removed as completely as possible, while bony structures remain. Radiation is applied to destroy the remaining tumour tissue in these structures. The surgeon needs to know exactly where the radiation tube is to be placed in the empty abdomen. To do so he needs to recognize structures reliably during the course of a surgical procedure, which can be difficult. Sometimes he has to recover from getting lost, because anatomical landmarks look similar and because blood in the surgical area makes it harder to discriminate.

In exploring support systems the full range of registration technologies was considered, comparable to Sections 5.2–5.4. These ranged from fully deformable registration, to magnetic tracked

objects (through anus and oesophagus) placed in the range of interest, to optical and/or magnetic tracking for tools (e.g., treatment tube) and to tracking the pelvis with a pointer held in the surgeon's hand (see Fig. 6). When balancing the pros and cons of each solution and discussing the options with the surgeon, it turned out that the solution with the biggest impact was also the cheapest and most simple, the 3D pointer. This pointer was one of the elements in a completely supported workflow with the other essential elements. The whole set was considered to have the most impact when the full spectrum of important issues for healthcare was taken into consideration: e.g., most significant reduction in errors by providing control and knowledge, essential advances in medical science, time to introduction, finances.

Conclusion (on registration in IORT): More advanced technologies are not always better at improving a specific situation. In fact, for some treatments a very simple form of registration can be most effective. A detailed understanding of the actual challenges posed to the user, as well as high-level professional goals, are crucial to define what is needed.

5.6. Conclusions on registration

Registration can be performed mentally or by the system. The mental task supported is orientation: knowing where one is in the world. The level of accuracy needed, as well as the speed of registration needed (how fast does the tissue move?) make a big difference in deciding what technology to use. By changing workflow the requirements for registration change and by changing the user interface a different type of registration can be used. High tech registration is not always the best solution; sometimes a simple solution is cheaper or more easily introduced in the work setting. The rapid introduction of less sophisticated devices can be better for the patient, because these can have a big impact right away.

Real-time deformable tissue registration (visualizing an entire moving liver, with all tissues shown at their actual location at all times) will be the next frontier, because it would enhance visualization and even control dramatically. In particular, if registration could handle deformations caused by tissue removals, minimally invasive surgery could benefit from this option. But for actual products to be implemented soon, it is better to make the biggest possible impact and learn from experiences in the field on how to design these dynamic interactions and the desired information support.

6. Team work aspects of collaborative co-design

6.1. Collaboration

Fig. 7 shows the organization of ARIS*ER at its start. User interfaces work package was seen as the connection between users and technology [57]. The required technical building blocks and development groups were structured according to discipline, and background technologies were regarded as interacting with foreground technologies.

Awareness was raised during the first 2 years. The UI researcher had to analyze user needs and workflow, while the technology partners were developing the identified technological building blocks set out in the ARIS*ER vision. The UI researcher first had to find a way to bridge between medical users and the engineers [58], and the Workflow Integration Matrix (WIM) served this purpose (see Section 4.5.1) [30–33]. Interactions with surgeons gradually increased, in the summer schools, in courses and during an actual surgery where there was discussion between the engineers and the operating surgeon. After this 2-year period of warming up the whole group of researchers was to take a next step: Stüdeli et al. developed and introduced a workshop method meant not only to bridge but also to encourage collaborative co-design [37,41]). In addition, Jalote-Parmar conducted a second WIM session, this time on liver resection. After these experiences all of the teams developed a richly collaborative co-design, mostly to develop the applications, but also for background technologies, where small groups of engineers collaborated. The planned network shown in Fig. 7 was no longer valid.

The tasks and roles assigned to partners were not so neatly organized between front and back end technologies. All partners were connected. For example, Kalkofen et al. reported: "Augmented-Reality guided treatment is typically targeted at a single phase or aspect in a surgical procedure" [59]. In ARIS*ER the intention was to integrate all phases and all aspects of work in a single system. For this Kalkofen and colleagues presented "component-

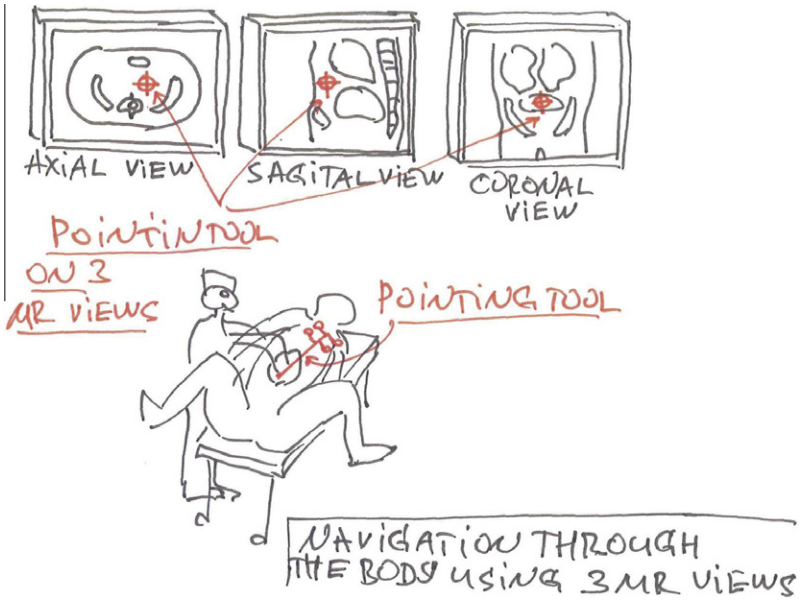

Fig. 6. One of the sketches made in the workshop. It shows the initial idea of providing a 3D pointer to provide orientation information during intra-operative radiotherapy. The surgeon points into the surgical area, where three coordinates are shown in the three standard orthogonal planes of preoperative imaging.

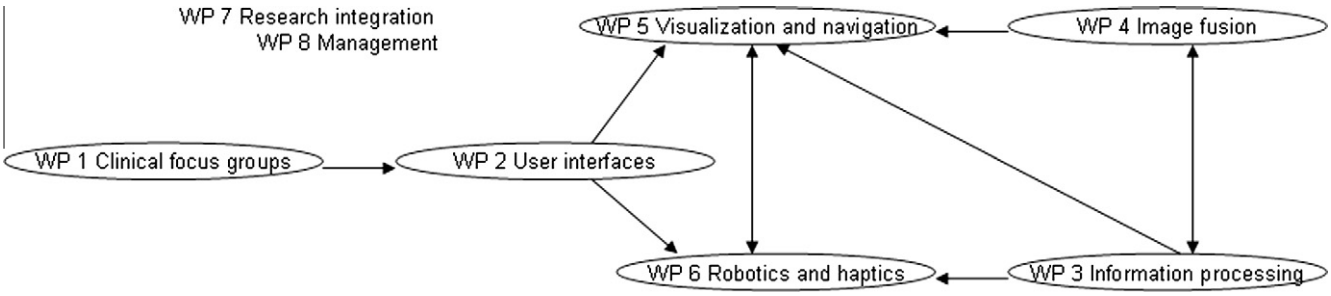

Fig. 7. Initial organization of work packages in ARIS*ER [57].

oriented software architecture ... for ensuring uniform application quality throughout the medical workflow and also the design of off-line and on-line image acquisition methods and methods for consistent management of modelling, processing and visualization of medical datasets throughout the medical workflow" [59].

Work package integration, a floating task in the initial model, became central in design work. Integration means matching technology components to user requirements and combining technical components to function as a whole. Roles in the team, including integration and field studies, were taken on by those who could best carry them out. Field studies were not restricted to the UI researchers; engineers also became involved and increasingly entered the OR.

The collaborative work between engineers began to resemble the network described by Klein et al. [10], with collaborative design performed by multiple participants (individuals or teams), each potentially capable of proposing values for design issues and/or evaluating those choices from their own particular perspective (e.g. robotics or imaging). Each person (or team) was concerned with a subset of design issues, with the links between the issues representing design issue interdependencies. All of the designers were collaborating to produce a complete design.

An understanding of how user needs were connected to the technologies developed and increasingly researchers took the mental step from their part of the design to the way the entire system would serve the user. Even though nobody knew exactly which parts would ultimately be integrated into the working demos everybody had a clear picture of their component in relation to the ARIS*ER vision, how their part related to current work problems, what the main design targets were, and why. Management steered design directions to end up with a completely connecting set, on an integratable platform.

The 2008 workshop gathered all the developed building blocks (parts and expertise), which were written down on paper. The goal was to build a demonstrator for each of the three applications so the building blocks were organized according to application. See Fig. 8 for the parts identified in the RFA case.

Note that it was researchers rather than management who conducted these integrations. Management staff steered the process, and also participated as members in the workshop. After the workshop the demonstrators were built and final patient and animal testing was conducted by the multidisciplinary collaborating teams.

6.2. From paradigm clashes to symbiosis

6.2.1. Understanding the differences between the domains

There were several differences in paradigms and experience between the disciplines, and mismatches in expectations for exchanges in knowledge occurred (see Table 2). Sometimes the approaches were complementary or facilitated the other's work. Recognizing differences and using them as an instrument in the development process was essential to developing team work.

To cope with the differences between the domains, communication in the multidisciplinary teams was mostly verbal, with some drawing and structural modelling on paper; it was hands-on during collaborative workshops and meetings held via Skype for research and design. The documents and literature produced in one domain often could not be used by the other team members, therefore, after learning from communication problems, more accessible forms of documentation were produced [41] (see Table 2, cell 6).

The main lesson the researchers learned was to recognize each other's expertise, to understand how to contribute and what the limitations of understanding are, which was especially important.

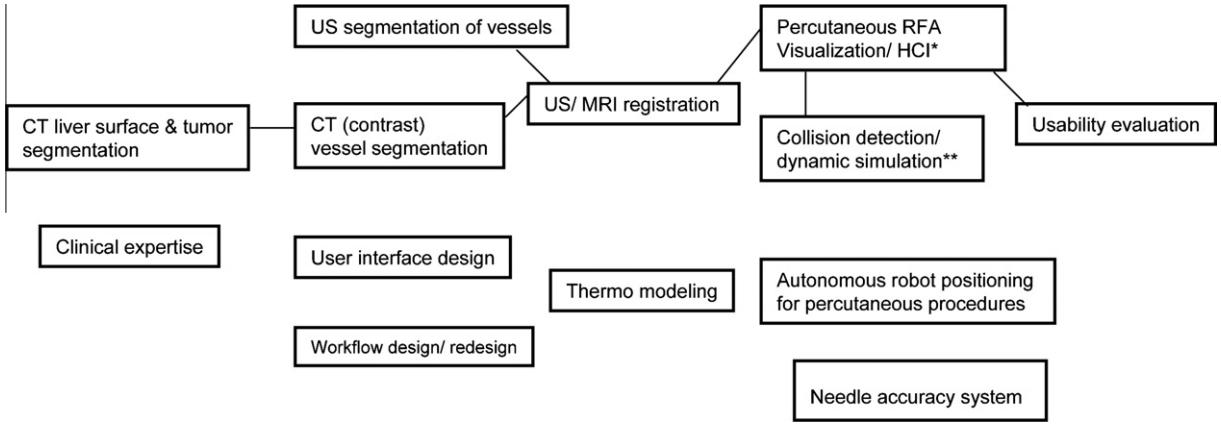

Fig. 8. ARIS*ER technical building blocks organized into a radiofrequency ablation (RFA) system in the 2008 workshop. * HCI = human–computer interaction. ** Collision detection = noticing approaching critical structures and signalling [60,61].

Table 2
Differences in paradigms and experiences between the disciplines.

1. Clinicians – technologists
Doctors have a decision-making pattern developed for diagnosis, treatment and evidence based medicine, which differs strongly from thinking patterns in engineers. Doctors (who do not work on collaborative design projects) have little idea of the developer's control over system behaviour and technological potential, nor do they have experience in providing useful input to design. They encounter difficulty when trying to envision what a new, non-existent technology would look like and how it would behave during use. They need presentations in order to imagine the experience of actual interaction. With actual prototypes they are able to experience the interactions, and new requirements can be formulated
2. Clinicians – industrial designers
Industrial designers have learned to work with doctors. They apply research techniques, which have been developed to tackle the problems mentioned in cell 1. For example, designers conduct ethnographic studies in the operating theatre, teach themselves medical jargon, study the cognitive processes of diagnosis and decision making, and conduct interviews and evaluations of design models. They have developed tailored methods to elicit tacit knowledge from users (that is, knowledge which is in the mind but cannot be expressed in words because it has a non-linguistic nature (intuition, emotion, motor skills). Tacit knowledge is often related to the most important product properties and is therefore very important
3. Between two engineering domains
Everyone involved in the research had a specialism with its own particular paradigms. For example, the mechanical engineers tended to solve a challenge through mechanical interventions (sensors, control loops, drivers); imaging developers would think of algorithms, calculating in 3D spaces; UI researchers would redesign task organization or would identify secondary safety risks. All of these parts are needed and together comprise the solution. Combinations were made in the network even though the researchers only partially understood each other
4. Computer graphics software engineers– UI researchers
The initial culture clash between computer graphics and industrial design was caused by the fact that computer graphics immediately starts to build prototypes, Very early many detailed UI decisions had to be made, such as colours, structural functioning elements, and type of display and computer graphics 'expected' industrial design to think in these terms at this stage. However, industrial design at that time was not concerned with these issues. Their order of working was to gain sufficient understanding first, then analyzing the problem, then advising technologists and beginning to move towards developing solutions much later. From the first user tests on symbiosis was experienced, because it was noticed that the pragmatic demonstrators (full of 'faults') still allowed heuristic evaluation sessions with doctors, which elicit crucial user knowledge. Some of this knowledge is almost impossible to attain by other available Human Factors/industrial design methods. The combination of advanced prototyping (with pragmatic design solutions) and analytic user studies strongly improved the quality of next demonstrators and final design outcome. Using just one of the two approaches would have been much less effective
5. Product management (industrial partners) – UI researchers
Product management in complex systems uses the knowledge that principal technology decisions are difficult to change later in the process. Product managers prefer to be completely sure about these decisions and therefore prefer to base their decisions on scientific facts. However, they are accustomed to the fact that not all of the parameters for design requirements are available early in the project. The managers from the industrial partners were especially pleased to have suitable, scientifically gathered information from users to guide their basic component decisions on
6. UI researchers – engineers
As technical developments progressed industrial designers investigated theoretical issues concerning user needs, for example, in relation to an evaluation framework [37], human navigation strategies and mental registration [36,49]. These theoretical investigations were presented to the technical partners, but they could not be used in their initial form. Stüdeli (UI researcher) described his personal experience as a member of the cardiac team: "After the project kick-off, additional interviews and observations of minimally invasive cardiac surgeries, and the (validated) problem analysis I arranged a follow-up meeting with the technical network partners. With the invitation I attached meeting minutes of the kick-of meeting and a functional description of a (possible) demonstrator. During the meeting the team further elaborated on technological opportunities for the detected user requirements. Only half a year later, during another follow-up meeting, I had to find out that the (my) functional description was written in such a way (e.g. use of ergonomic terms) that some of the engineering partners had missed the main message. Until then they solely relied on what has been orally explained (and understood) in the meeting. A similar communication experience also occurred when the first technical specifications and drawings where shared among the members of the development team. I hardly could understand them but I had foreseen to use them (directly) for the next steps in the "ergonomic process". The result of this was that we needed additional Skype meetings (www.skype.com) and face-to-face meetings with all involved partners for the general check for ergonomic problems, and also for the planning of the evaluation. The team had to learn (and also learned) to present (also in written form) the information in a more general and understandable language. Documentation for a specific field of research or discipline (e.g. supervisor, workshop) will most likely not receive the addresser outside this field." [41]

Every engineer tried his best to include all relevant factors, so it was disturbing to encounter misunderstandings and find that, for example, instructive documents created by one group were indecipherable to another. Once this was acknowledged, however, team work evolved into a new stage, which was based upon trust in one another's expertise, and in which it is more important to be aware what to ask, and when to provide information. This was not only true for the engineers, as the doctors also had to learn to provide information, to trust and to collaborate. In all cases the outcomes of research were the main trust-building factors: the doctors saw the designs, which were appealing and promising, and encouraged the engineers with feedback that was both positive and critical. In the end the doctors conducted animal and patient testing and therefore invested a great deal of extra time, which was proof that they believed the solution would be beneficial.

6.2.2. Using the differences between the domains

The last design case, for Intra-Operative Radio Therapy, became a kind of methodological round up. The researchers had established who to trust in user-centred research and design methodology and knew the potential of all of the researchers. They knew about the components developed earlier and their relation to basic/abstracted user requirements and had frequently joined creative design sessions to match requirements and system potential. Therefore they were ready to conduct an entire user-centred concept design process in 2 days, for a medical application most participants had never heard of (chapter 5.5).

They composed solutions with parts from any partner, without promoting 'their own' or pushing towards more 'interesting' technologies. They designed a mixture of complex and very simple solutions. They asked the doctor what he needed, and besides the expected *image guidance*, came up with *a support system for systematic data gathering for scientific research* and *support for treatment development and education* (these choices could have the largest impact on health care) [45]. Together, the two teams each designed the set of new components into a new system, built from ARIS*ER technologies and purchased parts.

While the new concept was designed difficult discussions took place concerning the recognition of what was an important detail and what was not; opinions differed, especially about the prospects of finding later solutions and estimating the severity of bottleneck situations. Since time was limited these issues had to be resolved very quickly. Experiencing the intense discussions made it clear that integration is almost synonymous with connecting requirements, downstream from users to technology and upstream from technology to user interface.

The speed demanded by the workshop organizers forced the participants in the two groups to work together in a constructive way, making their points clearly, while respecting each other's know-how. Differences in decision-making cultures were revealed: details/thoroughness versus pragmatism/global thinking. The dynamics of the pressure cooker, and the final very good result, improved understanding about differences between areas of expertise, and how to combine them.

6.3. Conclusions on the team work aspects of collaborative co-design

When entering into collaboration, learning proceeds in two phases:

(A) *Raising awareness*:

The researchers needed to learn about surgery. Group discussions with surgeons and watching live surgeries streamed via video were important. UI researchers had a role in organizing knowledge about the user and context and raising awareness. They presented structured overviews of the context and introduced methods for structured analysis sessions in workshops.

(B) *Shifting paradigms*:

(1) The engineers had to learn to step out of their own specific technology/component and assume system thinking, and work collaboratively with the other team members. The main lesson learned was to recognize each other's expertise, to understand how to contribute and what the limitations of understanding are. Team work skills are essential, and must be learned.
(2) The engineers had to learn to put the medical user at the centre. If system or parts requirements and technological possibilities did not seem to line up, re-studies had to be carried out. In the re-studies the best possible option for surgery was sought, whether a system redesign or a changed workflow, or both. The best clinical outcome, rather than the fanciest technology, was the goal. Meanwhile, there was a parallel effort to develop the more advanced technology.
(3) UI researchers and doctors also experienced a paradigm shift, learning to guide the multiple technologies. Generating proposed user requirements for technologies is not a simple process, and collaborating with engineers required the understanding that they work in a very different way.

7. The final collaborative co-design approach

This chapter integrates the findings in previous chapters and describes the actual ARIS*ER collaborative co-design. The process is sketched in Fig. 9, which shows the sequential tasks, iterative loops of activities and outcomes. The arrows show the sequential order of design activities. Three medical applications were developed in parallel (therefore, several activities are marked ''3x''). The model does not conflict with Fig. 3, but specifies how Fig. 3 was actuated. It does conflict with Fig. 7, which shows how the initial planned collaboration style between the disciplines changed during the process.

Since there were no comparable systems available yet, the starting point was just a general vision (see Section 1). First the essential building blocks (Section 4.2) were identified, along with related disciplines. Then the key issues (Section 4.3) and three representative medical applications (Section 4.4) were chosen. The essential building blocks were developed from the beginning (the four parallel arrows pointing down) using the vision as an initial design aim.

The UI researchers developed requirements per medical case (see Section 4.4) and universal user requirements. They initiated, stimulated and studied the development of collaborative co-design methodologies. Once they had the first iteration of the requirements available the iterations shown in Fig. 9 commenced. The user requirements fed the technologies. Eventually these grew into specifications. The potential of technology (shown on the left side), in particular the targeted ARIS*ER functionalities, were taken into account when defining requirements.

The technology building blocks were developed from the start, when user requirement investigations also began. Requirements had to be considered at different levels and could be changed in the process of the parallel development of system and workflow. However, if decisions had to be taken as technology was developed they were taken, even if (some) knowledge was lacking. One task was not delayed for another.

Early-stage demonstrators (see Section 4.5.1) were built and tested by users to reveal actual user needs, then redesigned to more accurate requirements. These demonstrators solved the problems end users encounter in attempting to envision what a new, non-existing technology will look like and how it will behave in actual use (see Table 2, row 1). Every part was designed by an

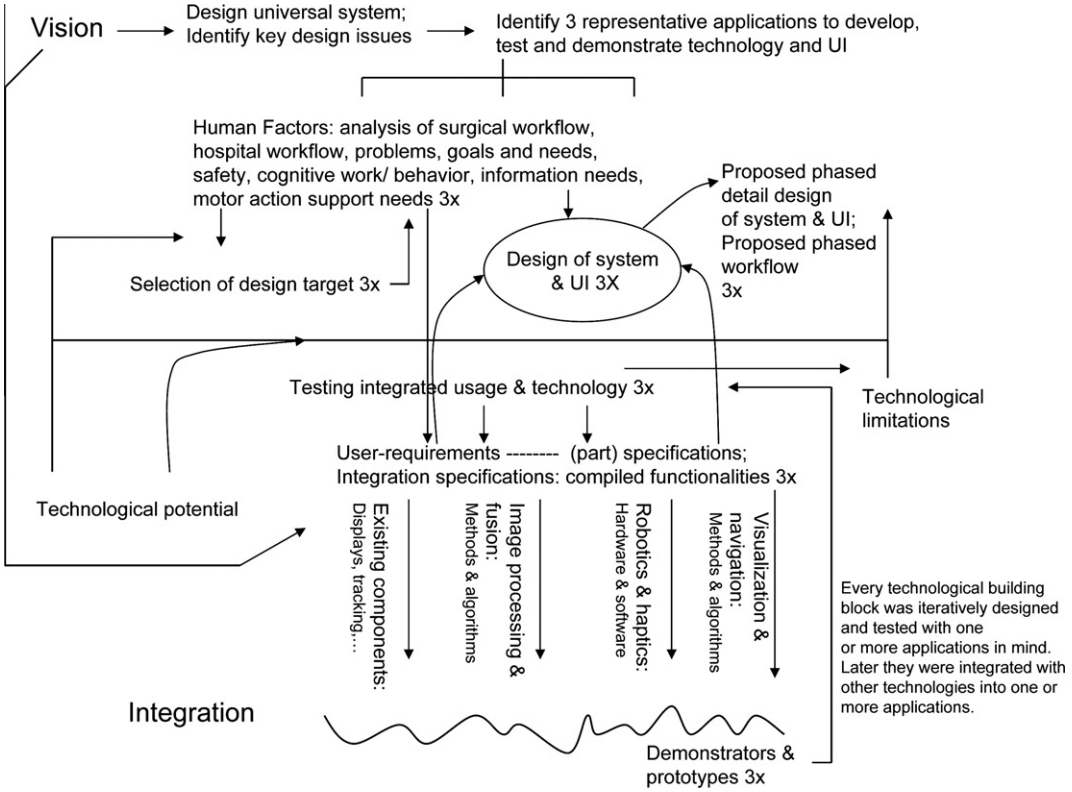

Fig. 9. The actual collaborative co-design in ARIS*ER. Design activities and outcomes are shown. Arrows indicate sequence in activities. The activities after "Identify 3 representative applications ..." are an iterative process, ending in the final designs (therefore the arrows go up and down, indicating circularity).

engineer who had the specific expertise required for that part, and every technology has a very wide set of opportunities and limitations. To develop an integrated system collaboration between the technologies was needed, as was state-of-the-art user research and interaction/ information design.

To allow this to work, engineers, Human Factors experts, industrial designers and end users had to work together. Since the majority of the team members had insufficient team work experience, training was needed in collaborative engineering, understanding partner domains, and conducting co-design. Each domain contributed to the team, and the opportunity to learn by doing was crucial. Awareness had to be developed first, which allowed paradigm shifts to take place in the minds of the researchers (see Section 6.3). Without this hands-on training, it is unlikely that this collaborative co-design method could have been developed or taken place.

Most of the envisioned software and hardware could be designed and built as planned, but since many parts had to be invented time pacing in research and development could not be fully controlled. During the project there were regular assessments of how long development would take, and if it was too long solutions had to be changed (see Sections 5.2 and 5.3). This is indicated as 'technological limitations' (right side). One way to bypass these limitations was to change the solution, or to introduce technology in the operating room in phases, starting with a 'simpler' version (final outcome, right top). In all three applications user testing was fully prepared, including both technology and medical workflow, and actual animal and patient testing was executed in two applications (see Sections 5.2–5.4). These preparations for tests forced the teams to integrate system, workflow and ethical considerations. This demand for integration is another positive aspect of developing prototypes for early testing.

The medical users were involved in the top and middle part of the scheme, not in strict technology development (the downward pointing arrows). In the centre of the scheme technology developments and Human Factors come together, and integration is key. Integration is almost synonymous with the connection of requirements, downstream from users to technology and upstream from technology to user interface.

To verify whether the ARIS*ER technologies would be generally applicable to other surgeries, the fourth design case (IORT, Sections 4.6 and 5.5) was organized. In a 2-day session, an open surgery was analysed with the help of medical experts and surgeons. On the second day new systems (compiled from ARIS*ER essential building blocks, with defined adaptations), user interfaces and workflows were designed and evaluated by a surgeon. He was very satisfied with the results. Indeed, his main concerns were addressed by the design, and he expected a significant impact on patient outcome. The conclusion was that the ARIS*ER technology building blocks can be used universally for other therapies with similar user needs. To do so requires a translational effort. The collaborative co-design methodology applied in the workshop naturally followed the same structure depicted in Fig. 9.

The second question was whether this translation could be made easily. This is doubtful, as the researchers were trained over a period of years and knew each other well. It would be unlikely for a new team to achieve this in the same amount of time, since that team would have to go through team training and the process of getting to know each other and establishing patterns of interaction.

8. Discussion

8.1. Comparing the new approach to real-world collaborative design

The design methodologies as well as the required team skills had to be developed because engineering sciences and medical sciences tend to be very separate, and expertise from industrial

design/Human Factors has been adopted by technology developers only to a limited extent. In this section the differences between current real-world collaborative design and the new approach will be discussed, including the consequences for management and for academic training.

"Even though real-world collaborative design clearly has top-down elements early in the process, the sheer complexity of many design artefacts means that eventually no one person is capable of keeping the whole design in his/her head and assessing/refining its global utility. Centralized control of the design decisions becomes impractical" Klein et al. [10]. This held true for ARIS*ER. The inter-disciplinary research team had a vague or nonexistent definition of the various management roles, which were assumed by different individuals in the course of the project. The management was concerned mainly with the overall process, i.e., the researchers joined the project for the duration of their contracts and worked on subprojects, while the board was concerned with the total process. However, the board members also participated in local subtasks.

Klein notes "the design process is dominated perforce by concurrent subsystem design activities (performed within the nodes) one in parallel with subsystem design consistency checks (assessed by seeing to what extent internode influences are satisfied)" [10]. Subsystems were indeed developed in parallel; and yes, they were developed to run on one platform for integration. But another crucial characteristic was the continuous effort to integrate (user-) requirements, in the building blocks, in the complete prototypes, and in the new workflow.

Klein assumes "that collaborative design as is currently practiced probably is quite prone to getting stuck in local optima that may be significantly worse than radically different alternatives. A reason for this would be that "designers are ... generally much more strongly encouraged to create a good design for their own subsystems, than to ... make someone else's job easier." [10]. In ARIS*ER the development of the demonstrators was not subject to egotistical thoughts or challenges. On the contrary, the collaborative teams sought constantly to optimize overall system performance and functions were easily shifted between the technology domains and to unexpected solutions. The demonstrators were important to them, with maximum medical outcome as target. They could approach it this way, because their prime academic achievement was their dissertation work. The researchers even tried to make their individual work on the demonstrators as easy as possible, but this did not mean that the demonstrators suffered.

Klein et al. [10] attempt to find solutions to the egocentric type of collaborative design, suggesting management techniques to influence negotiation outcomes in the process of trying to convince a designer to step back and hand over the 'fun stuff' to another designer. In ARIS*ER there were also negotiations but they were the opposite of what Klein et al. describe: the researchers did not make technologies more difficult and advanced to 'show off', but to optimize their clinical outcome. Diverse factors related to this include treatment quality, feasibility and time constraints. Demonstrator and prototype testing was used to identify requirements for the system and its parts and to identify priorities in design and the greatest total impact of technology measures.

The board management style in ARIS*ER was characterized by influence and inspiration rather than command, appropriate for a team of PhD students and postdocs. The selection of workshop topics and clinical and practical studies pushed by the board was not accidental. This gave direction and filled the researchers with the 'right' thoughts – workshops with no agenda would not have created synergies. Holes in the project were filled by permanent staff, without changing the largely self-directed research work of the hired scientists. This management style facilitated two key values for the researchers: the self fulfilling academic work as well as the motivation for research and prototyping fed by a deeper understanding of medical needs.

Klein et al. mention that "It is often unclear how to achieve a given set of requirements" [10]. In ARIS*ER there were no 'given' requirements. Generation of these requirements was a continuous part of development, and during the project some critical aspects of requirements kept shifting because of new insights. Furthermore, the requirements were not clearly divided among the technology building blocks – shifting between blocks was possible, and both workflow and task design could change requirements. The fact that innovations were needed made it unclear what can be demanded from the system. Some innovations were easy to realize, while others took more time, even too much time for the duration of the project. In such cases the only thing that could be done was to change something else, e.g. the workflow, or to change the set of requirements to solve the higher level aims.

The ARIS*ER approach is an answer to Klein's search for ways to encourage collaborative teams to take a systems approach, and to let designers of parts perform in the best way for the overall outcome. It provides answers to the problems of managing the overview of requirements and solutions which are too complex to manage centrally.

8.2. Educational consequences

Patel et al. [62] point out that there is a need for "a task analysis (including cognitive task analysis) of the [biomedical design] domain and its relationship to required competencies". One task in this domain is multidisciplinary collaboration between researchers. Its competency requires education and this was judged to be important to EU healthcare and economies and was leading in establishing ARIS*ER. Indeed, a few years ago it was noticed that the majority of available researchers have received no multidisciplinary training and have never encountered a real end-user.

There is a growing trend to train students in a more inter-disciplinary way, e.g. by conducting collaborations with end users, providing Human Factors courses, and training in making lists of surgery-centred requirements. Educational methods, however, remain immature, also because of a lack of proper methodologies to *uncover and match the benefits of the different disciplines to allow cross-fertilization*. Engineers have worked with medical staff, industrial designers have worked with medical staff, Human Factors researchers have worked with engineers, but before ARIS*ER these fields had not been brought together at one time in order to develop emerging multi-technologies. This combination brought together all the elements needed in ARIS*ER; all of the disciplines had to work together, and the parts could not be separated. The interface between the disciplines had to be managed. The gap between *emerging technology development* and *industrial design* is the deepest gap of all. These two areas should reach out to each other: technologists should not solely work with doctors, but should seek help for user-centred systems design and creative user interface for ease of use. Industrial designers should seek to work with the fundamental technology sciences in developing basic new possibilities for interaction. By doing so they can steer the coming interaction and information revolutions in a more human-centred direction, rather than only a push for technological gain.

Patel and colleagues state that that the appropriate method of education should be selected according to the teaching target and should include "lectures, small group interactions, and hands-on problem solving skills". To execute collaborative co-design the concept of 'small group interaction' has to be enlarged to include and combine the different disciplines. Inter-faculty projects with *all disciplines* are necessary: emerging technologies, industrial design, Human Factors and medical end users. Indeed, medical students should be on the team. The next generation of

medical professionals must also assume responsibility for technological developments in order to safeguard the quality of medical care and medical work.

9. Conclusions

ARIS*ER developed novel image guidance and cross-linked robotic systems to support minimally invasive surgery and intervention radiology. After 4 years of development the 16 full-time hired researchers (and several staff members) had generated new technological building blocks in a range of technological domains integrated into three systems (for radiofrequency ablation of liver tumours, endoscopic liver resection, and endoscopic mitral valve repair or replacement). One integrated system was tested with animals and one with patients. Although development was centred on these three applications the technologies can also be used to support other surgeries with similar design issues.

The ARIS*ER components can be adapted and compiled to support decision making and other mental tasks, e.g. to avoid or overcome disorientation, and to take over certain tasks, which could be improved by robots, e.g. precision placement of tools. In particular, the components of ARIS*ER can be used to represent the operative space (tissues, tools, lesions, tissue properties) and can support the user in navigating this space, both mentally and physically (with the tools).

To achieve a user-centred design several domains had to collaborate: engineers, Human Factors experts, industrial designers and medical experts. A multidisciplinary training programme was required, because researchers tend to be educated in a single discipline. Also, the methods for working together in a multidisciplinary way were structurally lacking, and their development became a parallel task. The final approach was called 'collaborative co-design'. It facilitates user guidance of the design process and also Human Factors/industrial design approaches, to achieve an optimal user interface design.

From the start, and working in parallel, universal components, integrated prototypes for specific applications, and user requirements were developed. Meanwhile the development of the 'more advanced technology' continued. This too was user-directed, but was aimed for the project's long-term vision. It became clear that striving for this vision should not hamper the rapid introduction of the new technologies in a clinical setting, because providing the user with a temporary but very effective tool best serves not only the patient and the clinician, but design as well, since new knowledge of actual requirements can be gathered to further steer technology development towards the vision.

We believe that the ARIS*ER approach solves current problems in collaborative teams, taking a systems approach and managing the overview of requirements and solutions, which is too complex to manage centrally. The key elements responsible for this are:

(1) The combination of engineering, Human Factors, industrial design and medical experts;
(2) The training researchers received in working in a multidisciplinary way (which is not a part of most academic education) in two phases: first raising awareness about the medical domain and gradually building understanding, trust and synergies between the disciplines;
(3) The two tasks assigned to researchers: investigation and a prototype stream, both connected to the end-user. Investigative work provides the necessary ego-centric scientific challenge, while work on the prototype provides practical relevance. Researchers were actively involved in the process of finding functionalities, finding required properties, solving technical problems, and optimizing the design decisions. Their practical experience taught them to step up from their personal components and regularly take a look at the total picture;
(4) The emerging technologies were characterized by various inventions, which were planned but without total time line control requiring regular assessments of (new) technological possibilities and limitations. Multiple iterations of the whole system pushed technology to the limits while requirements and solution spaces were changed several times;
(5) The active role played by industrial design and Human Factors in defining user needs, with help from the users. Over the course of the project engineers interacted more directly with medical staff, by the end all researchers were networked and working collaboratively;
(6) The development of tailored ergonomic methods; in this case concerning methods to define user requirements, to conduct co-design, and to evaluate solutions;
(7) The identification and immediate development of basic building blocks, even before the three applications were chosen. These building blocks and user requirements for the three applications were developed in parallel, neither waited for the other. Prototypes were used to get feedback from users to guide the technologies.

ARIS*ER was a subsidized project with a substantial travel budget and lots of room for free exploration. This probably promoted the unorthodox way of approaching the choice of targets and choice of solutions, as compared to 'classical' concurrent engineering. Having only a normal development budget and a strict timeline should not prevent developers from trying out the method. Provided all seven key elements are respected, the proposed method should also be useful for other emerging multi-technologies for the medical domain. The initial phase is likely to be difficult, because a rather large and diverse team is needed, and team learning is conditional, but once the researchers have acquired their skills development will speed up rapidly. Furthermore, by optimizing design team performance, user-centred design for complex medical domains can be brought to the next level, reducing safety hazards, providing missing information and fine-tuning workflow and technology.

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